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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WHEELER, THURMAN MICHAEL	
ART UNIT	PAPER NUMBER
1619	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,272	AJANI ET AL.	
	Examiner	Art Unit	
	Thurman Wheeler	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-33,45 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-33,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 23-33, 45 and 46 are pending

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 02/01/2011 has been entered.

2. Claim 23 has been amended.

3. Herein, claims 23-33, 45 and 46 are for further prosecution.

Claim Objection

4. Claim 23 is objected to because of the following informalities: the degree symbol for 90^{9}C, should be replaced with a zero, e.g. 90^{0}C. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
> 1. Determining the scope and contents of the prior art.
> 2. Ascertaining differences between the prior art and claims at issue.
> 3. Resolving the level of ordinary skill in the pertinent art.
> 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 23-33, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anisson et al (WO9513801, IDS) and in view of Bird et al (WO0202102, IDS) and Villa et al (EP 1183014, IDS).

Applicants' claimed invention is directed towards an oral pharmaceutical or dietary composition comprising an active ingredient and a complex sugar and/or dietary fibre, said active ingredient consisting of at least one short-chain fatty acid or salt, ester and/or amide thereof, in which the complex sugar and/or dietary fibre is selected from inulin, pectin, dextrin, maltodextrin or derivatives thereof and with one or more pharmacologically acceptable excipients, said composition comprising (a) a matrix consisting of lipophilic compounds with a melting point lower than 90°C and optionally amphiphilic compounds in which the active ingredient are at least partially incorporated, (b) an amphiphilic matrix; and (c) an outer hydrophilic matrix in which the lipophilic matrix and the amphiphilic matrix are dispersed.

Anisson teaches an oral pharmaceutical composition consisting of short chain fatty acids (SCFA) with carbon lengths of 2, 3 and 4, e.g. acetate, propionate and butyrate, which are bonded to a complex sugar, e.g. pectins, wherein any suitable source of pectin may be used such as high, medium and low methoxylated pectins (p.7, lns.10-14; p.8, lns.22-24, lns.35-36; p.9, lns.5-12; claim 5, 19, 20 and 21).

Anisson teaches SCFA are beneficial in facilitating transporting ions that play an important role in metabolism (p.4, lns.11-12). Furthermore, Anisson teaches a delivery mechanism that allows for delivery of short chain fatty acid(s) to the colon, and more preferably to the distal colon (p.7, lns.30-31; p.8, lns.8-10).

Anisson teaches that by ingestion of an agent comprising a SCFA (Short Chain Fatty Acid) covalently linked to a carrier, e.g. carbohydrate, that delivery of the SCFA can be effected to the colon (p.8, lns.8-10). Anisson teaches that the bond between the SCFA and the carrier is an ester bond, which can be hydrolyzed by the microbial flora of the large bowel (p.12, lns.1-3). Further, Anisson teaches the fatty acids are all susceptible to breakdown before arriving at the colon (p.8, lns.32-33). Accordingly, Anisson teaches delivery of short chain fatty acids (SCFA) to the colon that can be effected by covalently linking SCFA to a carbohydrate by an ester link.

However, the Annison reference does not embody the percent by weight of the fatty acids in a fatty acid delivery agent, or the incorporation of dietary fibre in the composition.

Bird teaches an oral method of delivering short chain fatty acids, preferably the fatty acid chain length is between 2 and 4, encompassing acetate, propionate and butyrate, such that the fatty acid is covalently bonded to a carrier molecule by a bond hydrolysable by bacterial hydrolases in the bowel to thereby release the fatty acid (p.5, lns.18-25; p.7, lns.1-4).

Bird teaches a formulation comprising between 0.1 and 50% by weight of the fatty acid delivery agent and most preferably between 0.5 and 20% (p.6, lns.19-20). Particularly, Bird teaches

the degree of substitution is selected from within the range of 0.05 to 1 SCFA per sugar moiety (p.17, lns.30-34). Furthermore, Bird teaches dietary fibres can be used as the carrier, these include soluble non-starch polysaccharides, i.e. pectin.

Accordingly, calculation using pectin wherein one sugar moiety of pectin is equal to about 170 g/mol, then the fatty acid such as acetate (60 g/mol) would provide between about 2% to 35% by weight of the fatty acid delivery agent within the range of 0.05 to 1 SCFA per sugar molecule in accordance with the teachings of Bird. Moreover, Bird teaches the degree of substitution of the fatty acid on the carbohydrate carrier coupled with the quantity of the agent ingested can be used to regulate the level of one or more SCFA delivered to the colon (p.15, lns.33 to p.16, lns.1-2).

Further, Bird teaches oral administration is by ingestion of a tablet, capsule or liquid into which the fatty acid delivery agent is incorporated (claim 32). Bird teaches the formulation may include a pharmaceutically acceptable excipient which may be any suitable excipient and in one preferred form it is water (p.6, lns.22-24).

Bird teaches that the three major acids, e.g. acetate, propionate and butyrate, stimulate muscular contraction and

enhance the flow of blood through the colon by relaxing the vasculature. Further, Bird teaches SCFA stimulate the absorption of fluid and this reduces the risk of diarrhoeal disease. Butyrate and, to a lesser extent, propionate act to maintain a normal population of colonocytes by opposing the growth of and promoting apoptosis of malignant cells (p.1, lns.27-33 to p.2, lns.1-2).

Villa teaches a controlled release and taste masking oral pharmaceutical composition containing an active ingredient, comprising (a) matrix consisting of the lipophilic compounds with a melting point lower than 90°C and optionally amphiphilc compounds in which the active ingredient are at least partially incorporated (b) an amphiphilic matrix; and (c) an outer hydrophilic matrix in which the lipophilic matrix and the amphiphilic matrix are dispersed [0018]. Furthermore, Villa teaches that this three component matrix structure can be used for the control of the dissolution of an active ingredient to modulate the dissolution of the active ingredient in aqueous and/or biological fluids, thereby controlling the release kinetics in the gastrointestinal tract [0001]. Villa teaches the compositions can further contain conventional excipients, i.e. chitosan and acrylic polymers [0034]. Villa teaches compositions in the form of tablets, capsules and minitablets (claim 10).

It would have been obvious to one skilled in the art at the time of the invention to modify the oral or dietary pharmaceutical composition containing short chain fatty acids (SCFA) as taught by Annison and Bird, as a whole, to provide a controlled release and taste-masking delivery system comprising a three component matrix whereby the active ingredient (i.e. SCFA) is released in the gastrointestinal tract as taught by Villa.

Furthermore, one skilled in the art would have been motivated to provide an oral pharmaceutical composition consisting only short chain fatty acids (SCFA) because SCFA play an important role in metabolism as taught by Anisson, and short chain fatty acids stimulate muscular contraction and enhance the flow of blood through the colon by relaxing the vasculature as taught by Bird. Moreover, one skilled in the art would have recognized the advantage of providing a composition consisting of a least one short chain fatty acid coupled to a complex carbohydrate, i.e. pectin, which is a dietary fibre, such that the fatty acid, e.g. acetate, propionate and butyrate, is covalently bonded to the dietary fibre polysaccharide by a bond susceptible to bacterial hydrolysis to provide release of the SCFA and also the dietary fibre in the bowel.

Thus, one of ordinary skill in the art would have had a reasonable expectation of success to provide a pharmaceutical composition as claimed by Applicants by following the teachings of Anisson, Bird and Villa, as a whole.

Accordingly, the claimed invention of instant claims 23-33, 45 and 46 were prima facie obvious to one skilled in the art at the time of the invention was made especially in the absence of evidence to the contrary.

Conclusions

6. Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thurman Wheeler whose telephone number is (571)270-1307. The examiner can normally be reached on 9:00 a.m.-5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Wax can be reached (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635